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RCQ REVIEW

Newsletter of the Office of Regulatory Compliance and Quality
United States Army Medical Research Materiel Command

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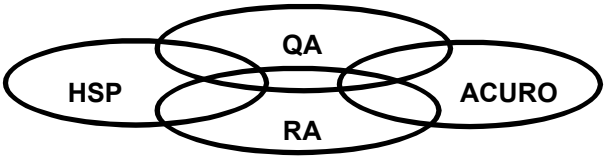
Office of Regulatory Compliance and Quality



MESSAGE FROM THE DEPUTY, REGULATORY COMPLIANCE AND QUALITY

Message from the Deputy, Regulatory Compliance and Quality…

Holiday Greetings from the Staff of RCQ. In has been our pleasure to serve you in 2003 and we look forward to providing you with even better service in 2004.

Our second issue of the RCQ review provides you with a number of important regulatory updates and insights. Late this fall the Army Surgeon General approved a change in the Human Subjects Research Review Board's policy regarding medical care for research-related injury – in this issue our attorney-advisor explains the revised policy. Ms Duchesneau and COL Pierson clarify the HSRRB requirements for reporting adverse-events and unanticipated problems encountered in the conduct of human subjects research. The Quality Assurance Branch tackles the challenge of "equipment qualification" in the context of FDA-regulated work and provides an update as to MRMC's system for health care provider credentials management. We conclude with our Hail and Farewells for 2003.

In 2004 RCQ will begin a robust schedule of staff assistance visits to assess and assist our Subordinate Commands' Human Subjects Protection Programs. Our Regulatory Affairs Branch is positioning itself to provide advisory support to investigators during protocol development and the Quality Assurance Branch is working closely with the MeRITs initiative to develop training solutions for the Command. Finally our Animal Care Use and Review Office is making great strides in addressing our non-human primate shortages. The RCQ Staff wishes you the happiest and safest of Holidays.

LAURA R. BROSCH
COL, AN
Deputy for Regulatory
Compliance and Quality

HSP

Human Subjects Protection & Regulatory Affairs Updates

RA

Medical Care for Research-Related Injuries: New Policy for USAMRMC Research Involving Human Subjects

On October 23, 2003, The Army Surgeon General approved a policy for the Surgeon General's Human Subjects Research Review Board (HSRRB), describing the requirements for medical care for research subjects who suffer research-related injuries. The HSRRB reviews research conducted, funded, or managed by USAMRMC, and the policy applies to all research reviewed by the HSRRB. HSRRB Policy Memorandum 2002-08, Version 02, is available through the USAMRMC website at http://mrmc-www.army.mil/ under Medical Research and Development, Regulatory Compliance and Quality Assurance (click on Human Subjects Protection). The policy reflects the mandates and goals of DOD regulations and directives, Army regulations, and Surgeon General regulations governing human subjects research.

The approved HSRRB policy can be found at: http://mrmc-www.army.mil/

The policy states that research subjects should be protected from research-related medical expenses to the extent possible. Subjects who are DOD healthcare beneficiaries (e.g., active duty military) are entitled to medical care for research-related injuries as provided under the DOD healthcare system. If a subject incurs expenses for such medical care that are not covered or reimbursed, the USAMRMC will consider requests for reimbursements. Reimbursement for these expenses cannot be guaranteed, however.

Subjects who are not DOD healthcare beneficiaries are eligible to receive no-cost medical care for research-related injuries in Army MTFs, pursuant to Army Regulation 40-400, paragraph 3-56. These subjects may also seek reimbursement from the USAMRMC for research-related medical expenses not otherwise provided or reimbursed. Again, reimbursement cannot be guaranteed.

The policy requires extramural research partners (i.e., non-DOD institutions that conduct research funded by the DOD) to include language in informed consent forms advising subjects of their right to no-cost medical care in Army MTFs for research-related injuries, and of the existence of a process to evaluate requests for reimbursement for medical expenses incurred to treat research-related injuries. This language is in addition to the institution's own language informing subjects of the institution's policy regarding medical care for research-related injuries.

For questions regarding this policy, contact Stephen Maleson, Attorney-Advisor, Office of the Staff Judge Advocate, USAMRMC, at Stephen.Maleson@det.amedd.army.mil.

Adverse Event/Unanticipated Problem Reporting: Who? When? Where? Why?

The requirements for reporting adverse events and unanticipated problems in the conduct of research are frequently misunderstood within the USAMRMC. The requirements for reporting to the local institutional review board (IRB) and Human Subjects Research Review Board (HSRRB) can be confusing. These requirements become even more complicated for Food and Drug Administration (FDA) regulated products that also require reporting to the IND/IDE sponsor. The purpose of this article is to describe the regulatory basis for reporting adverse events and unanticipated problems to both entities.

There's More to it Than Adverse Events: Reporting of Unanticipated Problems Involving Risks to Subjects and Others to the HSRRB

IRBs are charged with continuing review of ongoing research to ensure that the risk/benefit ratio continues to be acceptable. The risk benefit ratio may be affected by the occurrence of adverse events that impact subject safety. Therefore, it is important for IRBs to review adverse events to determine their impact on

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continuation of the research, to identify whether changes to the informed consent are required, and to assess whether subjects should be informed of additional risks and be re-consented.

The human subjects protection regulations 32 CFR 219 and 45 CFR 46 require that IRBs have written procedures for ensuring prompt reporting to the IRB, institutional officials, and the department or agency head of any unanticipated problems resulting in risks to subjects or others. Note that nowhere in these regulations are the words "adverse event." IRBs are responsible for determining what is meant by "prompt," developing an appropriate reporting procedure, and communicating this procedure to those engaged in research within the IRB's purview. Reporting procedures will differ from institution to institution, so it is important for investigators to identify the reporting requirements for all entities involved in review of the protocol and to clearly define the notification procedure within the protocol. The HSRRB has outlined its procedure in HSRRB Policy Memorandum 02-01, "Reporting to the HSRRB Unanticipated Problems Involving Risks to Subjects and Others" which can be found on the Human Subjects Protection page of the RCQ website. Reports submitted to the HSRRB fulfill the requirement of notification of the department or agency head.

21 CFR 312.32 provides definitions for a serious adverse drug experience and an unexpected adverse drug experience.

What is meant by "any unanticipated problems resulting in risks to subjects or others?" This statement encompasses more that what one usually thinks of as "adverse events." "Problems involving risk" may not necessarily result in physical harm. For example, losing a subject's study records containing identifiable private information results in the risk of breach of confidentiality. Confidentiality may or may not be breached, but either way this would be a reportable event. Another example would be administering the wrong agent to a subject at one time point in a series of vaccinations. Risks to others must also be reported. For example, inoculation of a household contact in a smallpox vaccine trial would be a reportable event. Problems resulting in risks to research team members are also reportable.

"Problems involving risk" may not necessarily result in physical harm.

When the research involves a FDA-regulated product, there are also requirements for reporting to the Sponsor and the FDA in addition to the IRB.

21 CFR 312.32 provides definitions for a serious adverse drug experience and an unexpected adverse drug experience:

"Serious adverse drug experience: Any adverse drug experience occurring at any dose that results in any of the following outcomes: Death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition (21CFR 312.32)."

"Unexpected adverse drug experience: Any adverse drug experience, the specificity or severity of which is not consistent with the current investigator brochure; or, if an investigator brochure is not required or available, the specificity or severity of which is not consistent with the risk information described in the general investigational plan or elsewhere in the current application, as amended (21CFR 312.32)."

In addition, ICH E6 guidelines define an adverse event as: "…any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event can therefore be any unfavorable an unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product."

The HSRRB uses the above-cited definitions to define serious adverse event and unexpected adverse event. Unanticipated problems are those problems that are not described in the protocol or other study documents. The current HSRRB policy requires that any unanticipated problems involving risks to subjects or

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others - to include serious and unexpected adverse events, regardless of relation to participation in the study, be reported **within one day** of the discovery of the unanticipated problem.

The HSRRB policy provides a sample reporting form that includes all of the required elements. Investigators may use this form if there is no equivalent available at their local institution. If the institutional form or study specific form does not contain all of the elements contained on the HSRRB reporting form, additional information may be requested from the investigator.

For studies with a medical monitor assigned, the investigator must inform the medical monitor of any adverse events. A medical monitor report that comments on the outcomes of the event and the relationship of the event to participation in the study must be submitted to the HSRRB within ten calendar days. The medical monitor should indicate whether he/she concurs with the details provided in the investigator's report. Follow-up reports should be submitted until resolution of the unanticipated problem. Appropriate supporting documents, such as laboratory reports, pathology reports, and discharge summaries should be submitted with the report.

Any changes to the HSRRB policy will be posted on the RCQ website & published in this newsletter.

Reports should be sent to the Acting Chair, HSRRB. The preferable mode of transmission is by facsimile to 301-619-7803 (DSN 343). Alternate modes of reporting include electronic mail to HSRRB@det.amedd.army.mil or telephone to 301-619-2165 (DSN 343). If reported by telephone, a written report should follow **within 3 working days**. Address the written report to the U.S. Army Medical Research and Materiel Command, ATTN: MCMR-RCQ, 504 Scott Street, Fort Detrick, Maryland 21702-5012. To facilitate reporting, include the HSRRB Log number ("A" number) for the protocol on any correspondence.

The HSRRB will evaluate reported information to determine if changes are warranted in the research protocol, protocol-related documents, and/or in the information provided to subjects. Any changes required by the local IRB should be communicated immediately to the HSRRB.

In addition to immediate reporting, adverse events and unexpected problems occurring during the reporting period should be described in the continuing review report submitted to the IRB of record and should also be summarized in the final report that is provided to the IRB of record at the conclusion of the study. In cases where the HSRRB is not the IRB of record, a copy of the continuing review report with documentation of the local IRB re-approval as well as the final study report must be submitted to the HSRRB for review. The HSP staff review these documents to ensure that any events that fit the criteria for immediate reporting have been reported to the HSRRB. If any events are identified that meet the HSRRB reporting criteria, further documentation may be requested regarding the event. Any information regarding adverse events or unanticipated problems received from other sites on multi-site protocols should also be provided to the HSRRB for review.

Any changes to the HSRRB policy on reporting of adverse events and unanticipated problems will be posted on the RCQ website (http://mrmc.detrick.army.mil**)** and published in this newsletter.

Expedited Reporting of Adverse Events to the HSRRB and to the IND sponsor

Expedited reporting requirements to the Sponsor of an investigational new drug (IND) are identified in 21 CFR 312.64(b). The Code of Federal Regulations requires investigators to notify sponsors promptly of adverse effects that can reasonably be regarded as caused by, or probably caused by, the drug. The regulation further requires investigators to notify Sponsors immediately of alarming adverse effects. It should be noted that the regulation does not require the investigator to make a determination of expected and unexpected - that determination is the responsibility of the Sponsor based upon a review of the event in relation to the known safety profile of the investigational drug. Furthermore, the regulation does not specifically define promptly and immediately with regard to notification of adverse effects and alarming adverse effects. It is the responsibility of the Sponsor working with the investigator during the writing of the protocol to identify mechanisms for periodic reporting of adverse events. Additionally, the requirement for reporting "alarming" adverse events is understood to mean those events that are "serious" as identified in 21 CFR

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312.32 (i.e., those that result in death, life-threatening situations, hospitalization, or prolongation of hospitalization). Immediate reporting means that at the time the investigator, a sub-investigator, or a clinical research coordinator becomes aware of the event, that the available information about the event is reported by the fastest means available (phone, fax, or e-mail).

TSG-Sponsored Investigational Drugs and Devices

To simplify reporting with U.S. Army Surgeon General (TSG)-sponsored investigational drugs and devices, notification of the HSRRB at 301-619-2165 or fax to 301-619-7803 will result in notification to the Sponsor. The RCQ staff will notify the U.S. Army Medical Materiel Development Activity (USAMMDA - TSG Sponsor's Representative) about the event upon receipt of a report involving a TSG-sponsored IND.

To facilitate the reporting, the call or fax should make clear that the report involves a TSG-sponsored IND, the name of the product, and the IND number assigned by the FDA.

Expedited reporting requirements to the Sponsor of an IND are identified in 21 CFR 312.64(b).

QA

QUALITY ASSURANCE UPDATES

EQUIPMENT QUALIFICATION – WHAT IS THAT?

What do you mean, "Is my equipment working properly? I get good results don't I?" or, "My customers seem satisfied." Do you? Are they? How do you know the results you are obtaining are "good" or satisfactory? First, you rely on a piece of equipment to analyze or perform some function. Then you add reagent or material to create a reaction. Then the machine performs as you expect it to and yields a result or a product. But how do you know that piece of equipment is performing to the standards you expect it or how do you know if you use another similar piece of equipment that you obtain the same results or product? In a regulated industry (of which we are a part for many of the products we test, develop or produce) the regulator (FDA) expects us to know the answer to those questions. While this may be the first time you have heard it, assuring equipment meets the criteria it purports to meet is not a new concept. This concept is known as "Equipment Qualification".

Equipment Qualification is the sum total of ensuring that a piece of equipment is appropriate for its intended use. There are 4 different phases of qualifications:

- Design qualification – Conducted at the development stage of the lifecycle of the equipment and consists of setting functional and performance specifications. Functional and performance specifications are considered when requesting a piece of equipment that you would consider suitable for conducting the analysis or making a product.
- Installation qualification – The purpose of installation qualification is to determine that the equipment is received as designed and specified, that it is properly installed in the selected environment you intend to use it and that the environment is suitable for the operation and use of the equipment.
- Operational Qualification – The process of demonstrating that the equipment will function according to specification in the selected environment.
- Performance Qualification – This phase demonstrates that the equipment consistently performs according to the specification appropriate for its use.

Completing all phases requires documentation to demonstrate to the non believer (auditor) that the equipment is qualified. Each phase of qualification requires a protocol, written and reviewed by the individuals conducting the testing as well as the recipient of the equipment. Each protocol must be approved by Quality Assurance prior to the conduct of the testing. Testing results and a study report reviewed and ap-

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proved by the same individuals as the study protocol must occur prior to the conduct of the next phase of qualification. Once the equipment qualification is complete, those documents should be maintained for the life of the equipment. All that hard work, before you even can begin to use the equipment! Unfortunately that does not end your commitment to ensure the piece of equipment operates in the manner it's intended. If repairs are required to the equipment, once the repairs are complete, you must ensure that the equipment is again operating properly. Dependent upon the amount of repairs required, at a minimum operational qualification must be completed and possibly performance qualification. Thus, equipment qualification is not a one time occurrence and the need for re-evaluation of the suitability of the equipment continues throughout the functioning life of the equipment.

Health Affairs Policy on Codification of Business Rules for Mandatory Inclusion of Certain Providers/Practitioners in the CCQAS

Effective 22 April 2003, the following list of providers/practitioners/ancillary personnel have been identified as critical for credentials management and will be supported by Centralized Credentialing Quality Assurance System (CCQAS):

Providers/Practitioners/Ancillary Personnel	
All physicians	**All clinical psychologists**
All dentists	**All occupational therapists**
All nurse providers – Advanced Practice Nurses, Nurse Practitioners, Nurse Midwives, CRNAs, etc.	**All audiologists**
All physical therapists	**All speech pathologists**
All podiatrists	**All physician assistants**
All optometrists	**All chiropractors**
All clinical dieticians	**All dental hygienists**
All social workers	**All mental health counselors**
All marriage and family therapists	**All professional counselors**

These requirements apply to:

1. **Active Duty** - Active duty record initiation will include not only staff, but also trainees in Service programs, Service sponsored civilian training, or long term civilian schooling (anyone counting against end strength).
2. **Reserve/National Guard**
3. **GS Civilian**
4. **Contractors**, and
5. **Providers working under resource sharing agreements**

The execution of this undertaking will be completed in two phases. Phase I includes establishing records for

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all physicians and dentists by 31 January 2004, to include, confirmation of the accuracy of this data with the providers. Additionally, needed by this date as well are expected completion dates to establish records for all the remaining provider categories in the list. Implementation of this latter process constitute phase II. Phase II is to be completed no later than 1 March 04.

Entering registered nurses, licensed practical nurses and all licensed vocational nurses is being delayed to focus on providers first; however, NLT 31 January 2004, the following is being requested:

- The mechanism you have established to track licensure among these three groups and how their professional credentials can be validated independently by an external source
- The operational mechanism you have established to provide the current status of the credentials of these individuals to gaining facilities when such individuals are transferred, deployed, or sent for backfill missions.

HQ, USAMRMC Licensure Credentialing and Privileging Office will facilitate the execution of this policy via scheduled Staff Assistance Visits (to begin Jan 2004) with the affected USAMRMC Major Subordinate Commands.

MEDCOM'S POLICY ON BASIC LIFE SUPPORT

MEDCOM's Policy on Basic Life Support (BLS) or Higher Level Training Course (effective 13 March 2001), is superseded by the current policy, effective 18 April 2003, which states:

As of October 1999, all healthcare personnel assigned to duties involving the provision of patient care must have current BLS training and certification. Current Advanced Cardiac Life Support (ACLS) or other advanced certification does not supersede BLS completion.

Commanders may grant exceptions to this requirement on a case-by-case basis for individuals such as part-time civilian consultants and faculty members. Said exceptions must be documented.

Per USAMRMC's Command Policy 2003-01, accessible upon request from this office, USAMRMC Licensure, Credentialing and Privileging Program, the Licensure, Credentialing and Privileging Office at HQ, USAMRMC, will work with the USAMRMC Laboratory/Institute Commanders/ Directors and their appointed Licensure, Credentialing and Privileging POC to ensure all assigned healthcare personnel are BLS trained and certified per MEDCOM's BLS Policy.

USAMRMC's BLS training and certification goal is to be 100% compliant NLT 18 April 2004.

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HQ, USAMRMC Licensure Credentialing and Privileging Office will facilitate the execution of this policy via scheduled Staff Assistance Visits (to begin Jan 2004) with the affected USAMRMC Major Subordinate Commands.

KUDOS FOR USAMMA

Please join us in congratulating the United States Army Medical Materiel Agency (USAMMA) for their 8 October 2003 International Organization for Standardization (ISO) 9000 Certification of their Quality Management System which supports the Maintenance Engineering and Operations Directorate (MEOD) and the MEOD's Depot level maintenance operations located at Tobyhanna, Pennsylvania, Hill Air Force Base, Utah, and Tracy California.

This certification was granted by SGS International Certification Services, Inc.

ACURO

Animal Care Use & Review Updates

Personnel Updates

As many of you already know, Ms. Joyce O'Brien retired from federal service in October. Joyce's position within the Animal Care and Use Review Office was that of Animal Use Review Specialist. During her tenure here she became the icon within the MCMR command to which many individuals looked for answers to their questions regarding the approval of research protocols involving animal use. She was the mainstay of our review efforts, and her leaving has created a void in the animal use review process within the Office of Regulatory Compliance and Quality. Efforts to fill the vacancy are ongoing as are our efforts to continue providing excellent customer service regarding animal use issues. During this interim period, the point of contact for protocol status inquiries will be Kathleen Dennis. She can be reached by commercial phone at 301-619-2283, DSN 343-2283 or by FAX 301-619-4165. Kathleen's email address is Kathleen.Dennis@det.amedd.army.mil. Your questions will be routed to the most appropriate staff member for a prompt reply.

RCQ Hails and Farewells

The Office of Regulatory Compliance and Quality (RCQ) would like to extend warm welcomes to four new members of our staff. They are Ms. Heather Feit, Mr. Brian Garland, Dr. Kamal Mittal, and Mr. Richard Potter.

Ms. Heather Feit, RAS Administrative Assistant

Ms. Heather Feit has joined RCQ as a Human Subject Protection (HSP) Administrative Assistant of the Research Administrative Branch (RAS). Heather brings with her three years of administrative experience from Dynport, a local vaccine company, were she worked with numerous business ops. Currently, Heather handles protocol triage and document management of all protocols that come into RCQ. She is also the point of contact for triage of human use protocols. Heather can be reached at 301-619-6987 or Heather.Feit@det.amedd.army.mil.

Mr. Brian Garland is RCQ's new Administrative Coordinator. Brian will be in charge of protocol document management. He is responsible for ensuring that all documents needed within a protocol are there before the study is issued to a scientific reviewer. Brian brings with him two and a half years of experience from Quintiles Transnational, a contract research organization. He worked in the Regulatory Affairs department reviewing informed consent forms, and writing and compiling IND, DMF, as well as BBIND submissions. In addition, Brian was a member of a submission work instruction task force responsible for standardizing the process for writing and compiling drug applications and submissions. Brian can be reached at 301-619-6242 or Brian.Garland@det.amedd.army.mil.

Mr. Brian Garland, RCQ Administrative Coordinator

Dr. Kamal Mittal joins RCQ as a Special Project Scientist. He brings with him 11 years of experience from the Office for Human Research Protections (OHRP) as an Assurance Coordinator. His duties included negotiating assurances of compliance with research entities, both domestic and foreign; providing guidance and regulatory interpretations to research institutions, investigators, government offices and the public; as well as educating personnel of research institutions regarding these policies and procedures. Dr. Mittal also played an extensively active role in developing OHRP's quality improvement program. Currently, he is conducting a Quality Assurance/Quality Improvement Assessment of

Dr. Kamal Mittal, RCQ Special Project Scientist

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MRMC's human research protection program. In addition, Dr. Mittal is also assisting in the development and completion of the various regulatory documents, such IRB membership rosters, assurances of compliance, and required written policies and procedures. Dr. Mittal can be contacted at 301-619-6657 or Kamal.Mittal@det.amedd.army.mil.

Mr. Richard Potter joins the Regulatory Affairs branch after a distinguished career as a Public Health Service Officer with the Food and Drug Administration. Rich most recently served as a scientific reviewer in the Division of Hematology of CBER where he reviewed NDAs, 510ks, and decision making processes regarding clearance or approval of new medical devices and drugs used in blood banking. Within RCQ Rich will be working on policy review and development. He will also be conducting regulatory reviews of investigational drug and device protocols. Rich can be contacted at 301-619-6241 or Richard.Potter@det.amedd.army.mil.

Mr. Richard Potter, Regulatory Affairs Scientist

Unfortunately, the RCQ family has lost several members of our team. We would like to say farewell to Ms. Robin Dillner, Ms. Joyce O'Brien, Dr. Suzanne Pursley-Crotteau, and Ms. Michelle Von Reichenbach. RCQ wishes these individuals the best of luck in their future endeavors. They will be missed dearly.

SAFETY TIPS FOR THE HOLIDAY SEASON

Provided by the Fort Detrick Safety Bulletin at http://www.detrick.army.mil

Fireplaces: You should not try to burn evergreens or wreaths in the fireplace or in a wood stove to dispose of them. They are likely to flare out of control and send flames and smoke into the room. Also, do not burn wrapping paper in the fireplace because it often contains metallic materials which can be toxic if burned.

Candles: Never use lighted candles near trees, boughs, curtains/drapes, or with any potentially flammable item.

Plants: Small children may think that holiday plants look good enough to eat. But many plants can cause severe stomach problems. Plants to watch out for include: mistletoe, holly berries, Jerusalem cherry, and amaryllis. Keep all of these plants out of children's reach.

Food and Cooking: The holidays often mean preparing large meals for family and friends. Wash hands, utensils, sink, and anything else that has come in contact with raw poultry.

Alcohol, Parties & Driving: Being a smart party host or guest should include being sensible about alcoholic drinks. More than half of all traffic fatalities are alcohol-related. Use designated drivers, people who do not drink, to drive other guests home after a holiday party.

Stress: The holiday season is one of the most stressful times of the year. You can't avoid stress completely, but you can give yourself some relief. Allow enough time to shop rather than hurry through stores and parking lots. Only plan to do a reasonable number of errands. When shopping, make several trips out to the car to drop off packages rather than trying to carry too many items. Take time out for yourself. Relax, read, or enjoy your favorite hobby at your own pace.

RCQ REVIEW

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http://mrmc.detrick.army.mil

SHARE YOUR LESSONS LEARNED

What does "Lessons Learned" mean? It most often means learning by that most memorable and painful of teachers - Experience.

The USAMRMC RCQ Lessons Learned Program promotes the sharing of knowledge across the USAMRMC complex with specific emphasis on lessons learned relevant to Human Subjects Protection, Quality Assurance and Regulatory Compliance in general. The result of sharing lessons learned are improved efficiencies and effectiveness, reduced risk and waste, as well as acceleration of remediation project closure.

The benefits of information sharing via the USAMRMC RCQ Lessons Learned Program include:

- Improved Safety
- Enhanced Cost Effectiveness
- Greater Efficiency
- Better Operational Results
- Fewer Repeat Mistakes

Share your stories, experiences and best practices with us and we will publish it in our quarterly newsletter. Email your lessons learned to Brenda.Meredith@det.amedd.army.mil or Shannon.Lertora@det.amedd.army.mil.

HELPFUL LINKS

• IRB Discussion & News Forum	http://www.irbforum.com/
• Army Publishing Directorate (Army Regulations)	http://www.usapa.army.mil/
• International Organization for Standardization	http://www.iso.ch/iso/en/ISOOnline.frontpage
• FDA: 21 CFR Part 11	http://www.fda.gov/ora/compliance_ref/part11/
• FDA: Device Advice website	http://www.fda.gov/cdrh/devadvice/
• DHHS: HIPAA impact on research	http://privacyruleandresearch.nih.gov/
• FDA: Regulating in vitro diagnostic devices (IVDs)	http://www.fda.gov/cdrh/comp/ivdreg.html
• Georgetown University Bioethics Library & Databases	http://www.georgetown.edu/research/nrcbl/
• Health and Human Services (HHS) Employee Locator	http://directory.psc.gov/employee.htm
• National Institutes of Health (NIH)	http://www.nih.gov/
• Army Medical Department (AMEDD)	http://www.armymedicine.army.mil/default2.htm
• Defense Advanced Research Projects Agency	http://www.darpa.mil
• DOD Small Business Innovation Research (SBIR)	http://www.acq.osd.mil/sadbu/sbir/homepg.htm
• Material Safety Datasheets (MSDS) Search Page	http://www.msdssearch.com/Default.htm